Question for written answer E-007080/2020
to the Commission
Rule 138
Joanna Kopcińska (ECR)

Subject: Responsibility of vaccine manufacturers and potential pathways for viral mutation

According to the ECDC's Risk Assessment, the new viral variant shows several mutations in the spike protein, including the receptor bindings, that could result in higher levels of transmission. Most of the new vaccine candidates are based on a specific sequence of the viral spike protein. The ECDC clearly stresses the importance of monitoring changes in the spike protein of circulating SARS-CoV-2 strains and of assessing possible antigenic changes. However, the antigenic characterisation of the new variant is still ongoing and the results are not expected for a number of weeks.

On the one hand, it will be important to monitor the efficacy of the COVID-19 vaccines as they are used in the field, including through assessing their impact on the different variants of the virus. But on the other hand, surveillance and checks in the event of the possible failure of previously developed vaccines in the face of the new viral variant may help us to understand what their true efficacy is.

In what way are the entities responsible for developing the vaccines – including the vaccine awaiting conditional marketing authorisation at the beginning of 2021 – required by the Commission to monitor the pathways of this particular mutation, potential future mutations and ongoing changes in the spike protein among circulating variants of the SARS-CoV-2 virus.

To what extent are these entities obliged to continuously assess possible antigenic changes on an ongoing basis?